DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 10, 2015

Hill-Rom
Ms. Ann Waterhouse
Director, Regulatory Affairs
1069 State Route 46 East
Batesville, Indiana 47006

Re: K143414
Trade/Device Name: Hill-Rom Wireless Connectivity Module
Regulation Number: 21 CFR 880.5100
Regulation Name: AC powered adjustable hospital bed
Regulatory Class: II
Product Code: FNL
Dated: January 29, 2015
Received: January 30, 2015

Dear Ms. Waterhouse:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143414

Device Name
Hill-Rom Wireless Connectivity Module

Indications for Use *(Describe)*
The intended use for the Hill-Rom Wireless Connectivity Module is to assist clinical staff to monitor bed parameters on specific Hill-Rom beds. The Hill-Rom Wireless Connectivity Module is intended to be used only with specifically enabled Hill-Rom beds that have been verified and validated with the Hill-Rom Wireless Connectivity Module, and is not intended to provide bed status information for non-Hill-Rom beds. The Hill-Rom Wireless Connectivity Module is not intended to permanently store any type of data. The Hill-Rom Wireless Connectivity Module is not intended to provide automated treatment decisions or as a substitute for professional healthcare judgment. The Hill-Rom Wireless Connectivity Module is not a replacement or substitute for existing alert equipment. All patient medical diagnosis and treatment are to be performed under direct supervision and oversight of an appropriate health care professional.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Traditional 510(k): Hill-Rom Wireless Connectivity Module

510(k) Submitter: Hill-Rom
1069 State Route 46 East
Batesville, IN 47006
Registration Number: 1824206

Contact Person: Ann Waterhouse, RAC
1069 State Route 46 East
Batesville, IN 47006
812-931-3426 (telephone)
812-934-1675 (facsimile)

Date Prepared: 25 November 2014
Trade Name: bed, ac-powered adjustable
Common Name: Hill-Rom Wireless Connectivity Module
Review Panel: General Hospital
Classification Name: bed, ac-powered adjustable (21 CFR 880.5100, Product Code FNL)
Predicate Name: iBed™ Wireless with iBed™ Awareness, K103536

Device Description

The Hill-Rom Wireless Connectivity Module is a wireless module installed on specific Hill-Rom bed models. The Hill-Rom Wireless Connectivity Module is integrated into existing bed platforms via a USB connection to the bed's electrical system and provides connectivity to a remote server application.

The Hill-Rom Wireless Connectivity Module is used to assist staff to monitor hospital bed status and to assist the healthcare provider in providing patient care. The optional feature is mounted onto Hill-Rom hospital beds to wirelessly transmit bed information such as: bed exit status, bed side rail status, bed brake status, head of bed angle, and patient weight from bed scale. The Hill-Rom Wireless Connectivity Module is a tool that facilitates the wireless transmission of the bed status data using a wireless hardware and software device which communicates with a remote server in the hospital. The bed status data may be displayed at user-defined locations, such as nursing stations. It may also be shared with EMR (Electronic Medical Record) Systems through integration with 3rd party systems.

Intended Use

The intended use for the Hill-Rom Wireless Connectivity Module is to assist clinical staff to monitor bed parameters on specific Hill-Rom beds. The Hill-Rom Wireless Connectivity Module is intended to be used only with specifically enabled Hill-Rom beds that have been verified and validated with the Hill-Rom Wireless Connectivity Module, and is not intended to provide bed status information for non-Hill-Rom beds. The Hill- Rom Wireless Connectivity Module is not intended to permanently store any type of data. The Hill-Rom Wireless Connectivity Module is not intended to provide automated treatment decisions or as a substitute for professional healthcare judgment. The Hill- Rom Wireless Connectivity Module is not a replacement or substitute for existing alert equipment. All patient medical diagnosis and treatment are to be performed under direct supervision and oversight of an appropriate health care professional.

Patient Population

The patient population is determined by the medical bed to which the Hill-Rom Wireless Connectivity Module is affixed, however, the use of the wireless module does not change the existing populations which these beds serve, they remain: Critical care, in-patient acute care, step down/progressive care, Medical /surgical, high acuity sub-acute care, post anesthesia care unit (PACU), sections of the emergency department (ED), extended care, long-term care, and skilled nursing facility care.

Comparison of Technological Characteristics

The Hill-Rom Wireless Connectivity Module uses the same fundamental scientific technology as that of the iBed™ Wireless with iBed™ Awareness. Both have the ability to communicate bed status through wireless means. Both accessories are meant to operate with existing hospital bed products. Neither device specific for the purposes of wireless capability: (1) affect the intended use or (2) alter(s) the fundamental scientific technology of the devices to which they are affixed.

Substantial Equivalence

The Hill-Rom Wireless Connectivity Module is equivalent to the previously cleared and commercially distributed iBed™ Wireless with iBed™ Awareness (K103536) in that the Hill-Rom Wireless Connectivity Module is intended to assist clinical staff to monitor bed parameters on specific Hill-Rom beds, and the Stryker iBed™ Wireless with iBed™ Awareness (K103536) is intended to monitor bed parameters of the Stryker product. Both accessories use the same wireless technology (IEEE 802.11), and because they

are for use with hospital bed products, they must adhere to similar design considerations regarding the product to which they are eventually paired. The energy expectations are those of wireless technology, as are the operating principles.

Non-clinical performance data

Hill-Rom has verified and validated that the Hill-Rom Wireless Connectivity Module meets its functional, performance, safety and efficacy specifications and requirements. Software testing and hardware testing of the final device has been conducted. The device has been tested according to National and International Standards for compliance to these recognized Consensus Standards below:

N/A	EN	EN 55024:2010	Immunity characteristics - Limits and methods of measurement	Jan 2011	Electromagnetic immunity of information technology equipment.
N/A	EN	55022:2010	Radio disturbance characteristics - Limits and methods of measurement	Jul 2011	Information technology equipment, radio disturbance characteristics.
5-67	IEC	62366:2007/(R)2013	Medical Devices - Application of usability engineering to medical devices.	Jul 2014	(General I (QS/RM))

The performance testing that has been conducted on the Hill-Rom Wireless Connectivity Module demonstrates that it is as safe and as effective, and performs as well as the predicate device.

Clinical Testing

The Wireless Connectivity Module communicates existing bed status data. Clinical testing was therefore not required for determination of substantial equivalence as there is no new data involved in the wireless communication, subject of this submission.

Conclusion

The data herein supports this device, the Hill-Rom Wireless Connectivity Module, as safe and efficacious as that of the Stryker iBed™ Wireless with iBed™ Awareness, K103536, predicate device and is therefore, substantially equivalent.